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189 3

12/07/90

☑ This application has been examined ☑ Responsive to communication filed on amend. a Sept. 13, 1990 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892. (1 page)
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1, 19, 20 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 2-18 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 1, 19, 20 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are not acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

By Preliminary Amendment of 13 September 1990 claims 2-18 have been cancelled. New claims 19 and 20 have been added. Therefore, claims 1, 19 and 20 are pending in this Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The specification is found objectionable regarding the incomplete entry of Cross-Reference to Related Applications because: The title for this section is missing and the status of each application would have to be set forth.

OK

The specification is found objectionable regarding the use of BMP "in another most preferred embodiment, --- purified PDGF and purified BMP---" page 4, last 4 lines. What is "BMP"?

OK

The figures as presented are not acceptable for examination purposes. For example, on page 11, line 3, "arrow 30" is not seen anywhere in any of the figures.

The specification is found objectionable regarding the alleged utility i.e. a method of or for promoting bone, periodontium, or ligament growth of a mammal (living) using a GF.

There is no evidence that such a method would be applicable to healthy individuals having normal bone, periodontium, or ligament. One of skill in the art is not likely to accept such an allegation without proof. The specification is totally devoid of any proof that using GF would promote bone and etc. in all living (healthy or not) mammals. Therefore, the operability and utility as claimed is questionable. Moreover, the scope of the claims are not warranted by the instant enablement.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

The attempt to incorporate subject matter into this application by reference to the US Patent Applications as set forth on the first paragraph of page 1 of the specifications is improper because Incorporation by reference can be made only by (a) a US Patent or (b) an allowed US Patent Application. See MPEP 608.01(p), Section B.

Claims 1, 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 19 and 20 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term " damaged" in claim 19, line 3, fails to find antecedent basis in the earlier part of the same claim.

Claim 20 is indefinite regarding the use the term, "planning". Note on page 6, line 30 and page 11, line 5, the same term is written as "planing". Clarification and correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 19 and 20 are rejected under 35 U.S.C. § 102(a), (b) and (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Terranova et al. (US Patent No. 4,702,734, filed May 8, 1986).

The reference teaches a method of promoting periodontal regeneration comprising conditioning of root dentin and exposing the tubules, applying a cell growth factor to the site being treated. See the entire document particularly column 3, line 64 to column 4, line 24. Claim 1 is anticipated over the art. Claims 19 and 20 are inherently anticipated and/or obvious in view of the prior art. Preparing for conditioning of root dentin

either by mechanical or chemical means prior to the application of the active agent, GF, does not render patentability to the claimed methods because in either case the object is to clean the site before GF application. Therefore, evidence of unobviousness is required for the patentability.

Applicant is requested to submit a copy of the references cited on pages 1 and 2 of the specification together with a form PTO 1449 in accordance with MPEP 609 and 37 CFR 1.56, 1.97-1.99 for consideration by the examiner in responding to this Office action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Moezie whose telephone number is (703) 308-3529.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

F. T. Moezie

F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
ART UNIT 189

Moezie/bg
December 06, 1990